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86175 7590 06/24/2010 Pillsbury Winthrop Shaw Pittman LLP			EXAMINER	
(INTEL)			WRIGHT, PATRICIA KATHRYN	
P.O. Box 10500 McLean, VA 22102			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/748,389 YAMAKAWA ET AL. Office Action Summary Examiner Art Unit P. Kathryn Wright 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 06 April 2010. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.10-17.19-22.31-40.64-66 and 68-73 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1,10-17,19-22,31-40,64-66 and 68-73 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 29 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Notice of Draftsperson's Patent Drawing Preview (PTO-948). Paper No(s)/Mail Date. ___ 5) Notice of Informal Patent Application

Paper No(s)/Mail Date

3) Information Disclosure Statement(s) (PTO/SB/08)

6) Other:

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DETAILED ACTION

Status of the Claims

 This action is in response to papers filed April 06, 2009 in which claims 1, 22, and 68-69 were amended.

The amendments have been thoroughly reviewed and entered. Any objection/
rejection not repeated herein has been withdrawn. Applicant's arguments have been
thoroughly reviewed but are deemed moot in view of the amendments, withdrawn
rejections, and new grounds for rejection. New grounds for rejection, necessitated by
the amendments, are discussed.

Claims 1, 10-17, 19-22, 31-40, 64-66, and 68-73 are under prosecution.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the recitation that the upper substrate comprising a first cavity or the lower substrate member a second cavity wherein a portion of the porous silicon membrane is located in a hollow space formed by the first or second cavities must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abevance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the recitation that the upper substrate comprises a first cavity or the lower substrate member comprises a second cavity wherein a portion of the porous silicon membrane is located in a hollow space formed by the first or second cavities does not find antecedent basis in the original specification. However, the original specification does support a recess 124 formed in either the upper or lower substrate member (see paragraphs [0027] and [0037]).

The rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that

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the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - Resolving the level of ordinary skill in the pertinent art.
 - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 10-17, 19-22, 31-40, 64-66, and 68-73 are rejected under 35 U.S.C.
 103(a) as being unpatentable over Freeman et al., (US Patent Pub. No. 2003/0104512), hereinafter "Freeman".

As to independent claims 1, 22, 68 and 69, Freeman teaches a microfluidic device (see paragraph [0001]), comprising:

a source fluid flow channel (reads on upward extending well 16), see paragraph [0044];

a target fluid flow channel 28 in fluid communication with the source fluid flow channel at a cross-channel area (at test site 18), wherein the source fluid flow channel crossing over the target fluid flow channel at the cross-channel area 18, see embodiment of Figs. 1 and 5 and paragraph [0045];

a porous membrane 14 separating the source fluid flow channel from the target fluid flow channel in the cross-channel area, wherein the porous membrane comprises a porous silicon membrane (see paragraph [0029]);

a substrate comprising an upper substrate member 20 and a lower substrate member 10; and

a field-force/gradient mechanism (electrodes 26, 34) proximate the porous silicon membrane, wherein the field-force/gradient mechanism comprises an electric field configured to produce a fluid movement of a fluid from the source fluid flow channel to the target fluid flow channel via the porous silicon membrane located in the cross-channel area. Freeman teaches the fluid movement of the fluid from the source fluid flow channel to the target fluid flow channel via the porous silicon membrane located in

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the cross-channel area is produced solely by the field-force/gradient mechanism. That is, Freeman uses global hydraulic to move the fluid along channels to the microwells, how fluid flow across the membrane itself is solely controlled by drive voltages across each opening in the membrane (see paragraph [0045]).

It is noted that Applicant teaches the use of porous polysilicon membrane (e.g., PPSi), see the original claims and paragraph [0039] of Applicant's specification. Thus, the porous polysilicon membrane of Freeman is a sensor that does necessarily exhibit a sensing characteristic causing a change in at least one of the optical characteristic and the electrical characteristic in response to exposure to a targeted fluid or reaction, since the membrane structure recited in the Freeman reference is identical to that of the claims, claimed properties or functions are presumed to be inherent. See . MPEP 2112.02

Freeman teaches the source fluid flow channel is within the upper substrate 20 member and the target fluid flow channel is within the lower substrate member 10 and the porous silicon membrane is an integral part of the substrate. Freeman also teaches a substrate having recesses 140 for holding a plurality of membranes, see Fig. 6 and paragraph [0050].

Freeman does not specifically teach that the source fluid flow channel crosses over the target fluid flow channel in a "X fashion" at the cross-channel area or that the upper substrate member comprises a first cavity and the lower substrate member a second cavity, and wherein a portion of the porous silicon membrane is located in a hollow space (i.e., recess) formed by the first or second cavities. However, it would

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have been obvious to one of ordinary skill in the art at the time of the claimed invention to form a cavity in both the first and second substrate of Freeman so that the membrane is located therein since the recess created would help hold the porous silicon membrane in place for subsequent handling and prevent wrinkling or deforming of the membrane during use. In addition, the arrangement of the source flow channel crossing over the target flow channel in a X fashion is a mere rearrangement of parts. It has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

Regarding claims 10 and 31, Freeman teaches fluorescence spectroscopy and imaging (a light source 166 and a detector 170) focused at the membrane cross-channel area (see paragraph [0052]).

As to claims 11 and 32, Freeman teaches the thickness of the porous silicon membrane is between 0.01 and 50 micrometers (i.e., 4 to 20 microns), see paragraph [0029].

With respect to claims 12 and 33, Freeman teaches the porous silicon membrane is capable of fractionating molecules based on size, molecular weight, charges, chemical affinity or other chemical/physical properties (see for example paragraph [0041]).

As to claims 13 and 34, Freeman teaches the porous silicon membrane is made of a single crystal porous silicon (Psi), see paragraph [0029].

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Regarding claims 14 and 35, Freeman teaches wherein the porous silicon membrane is made of a porous polysilicon (PPSi), see paragraph [0029].

With respect to claim 15, Freeman teaches the source fluid flow channel and the target fluid flow channel being formed in the substrate, see Fig. 1.

As to claims 16, 17, 36 and 37, Freeman teaches the substrates 20, 10 are made of polydimethyl siloxane (PDMS), silicon, quartz, etc., see paragraph [0050] and [0052].

With respect to claims 65, 66, and 70-73, as discussed above, Freeman teaches the membrane consists of porous polysilicon membrane 14 (see paragraph [0029]). It is noted that Applicant teaches the use of porous polysilicon membrane (e.g., PPSi), see paragraph [0039] of Applicant's specification. Thus, the porous polysilicon membrane of Freeman does necessarily exhibit the property of being a passive diffusion barrier between the source fluid flow channel and the target fluid flow channel, since the membrane structure recited in the Freeman reference is identical to that of the claims, claimed properties or functions are presumed to be inherent. See . MPEP 2112.02.

As to claims 19, 20, 39 and 40, please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., disposed or reused) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. Freeman inherently teaches the device is a disposable or reusable since any device can be disposed of or reusad.

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As to claims 21 and 64, Freeman teaches wherein the source fluid flow channel and the target fluid flow channel intersect at a 90 degree angle at the cross-channel area, see embodiment of Fig. 5.

Double Patenting

- 8. The provisional rejection of claims 13-14 and 34-35 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 38-39 and 41 of copending Application No.10/856,372 is held in abeyance until indication of allowance of the claims.
- 9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Applicant is advised that should claims 1, 10-17, 19-22, 31-40, 64-66, and 68-73 be found allowable, claim 1 and 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Similarly, claims 68 and 69 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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12. Claims 1, 10-17, 19-22, 31-40, 64-66, and 68-73 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 12/655,431. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 of '431 are directed to the same subject matter and fall entirely within the scope of claims 1, 22, 68 and 69 of the instant application.

Both claim an apparatus comprising a substrate having defined therein, a source microfluidic channel in fluid communication with a target microfluidic channel with a semi-permeable porous membrane positioned between the source and the target flow channel and field-force/ gradient mechanism configured to produce fluid movement across the membrane.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

 Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection, as set forth above.

Conclusion

- 14. No claims are allowed.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/ Primary Examiner, Art Unit 1797